



To: Cannabis Control Board
From: Jessa Barnard and Jill Sudhoff-Guerin, Vermont Medical Society, Stephanie Winters, American Academy of Pediatrics VT Chapter and Vermont Psychiatric Association
Date: October 21, 2021
RE: Cannabis Regulation Feedback

On behalf of the over 2,000 physician and physician assistant members of the Vermont Medical Society (VMS), the American Academy of Pediatrics Vermont Chapter (AAPVT) and the Vermont Psychiatric Association, we appreciate you considering our feedback on several areas of regulation currently before the Cannabis Control Board (CCB).

Specifically, VMS submits comments at this time regarding:

- (1) Warning label addition to include acute physical and mental health risks;
- (2) Advertising proposal that does not promote cannabis use and limits exposure of cannabis advertising to persons under the age of 21;
- (3) Whether integrated licensees and product manufacturers licensees should be permitted to produce solid concentrate products with greater than 60 percent THC for purposes of incorporation into other cannabis products;
- (4) Whether the Board should permit hemp or CBD to be converted to Delta-9 THC and, if so, how it should be regulated;
- (5) Recommendations for the membership and duties of the Medical Cannabis Oversight Advisory Panel; and
- (6) Other recommendations regarding the future regulation of cannabis for symptom relief.

1) Warning label to include acute physical and mental health risks associated with cannabis use

VMS supports the recommended warning label and warning symbols as considered and supported by the CCB Public Health Subcommittee at their October 18, 2021 Meeting. VMS also recommends that these conditions are added to this sentence in the warning label: “Cannabis may be habit forming, can impair concentration, coordination and judgement, **and can cause uncontrolled vomiting, psychosis, and suicide attempt.**”

Cannabis use is associated with increased urgent and emergency department psychiatric visits and increased mental health disorders including psychosis. According to a January 2020 report presented by the Vermont Department of Health, cannabis use can lead to the development of schizophrenia or other psychoses, as well as suicidal ideation and suicide completion.¹ A 2019 study published in the Lancet found that the strongest independent predictors of whether any given individual would have a psychotic disorder or not were daily use of cannabis and use of high-potency cannabis.² Currently, habitual users of marijuana are going to emergency rooms complaining of bouts of uncontrollable vomiting related to their frequent cannabis use. This condition, named “cannabis hyperemesis syndrome,” has been shown to subside when the consumer stops using cannabis products.³

Therefore, VMS feels that the warning labels must include these acute risks of acute physical and mental health reactions in order to adequately warn new users of the increased occurrence of uncontrolled vomiting, psychosis, and suicide attempts associated with cannabis use. These warnings should also be included on all product packaging and advertising.

2) Advertising proposal that does not promote cannabis use and limits exposure of cannabis advertising to persons under the age of 21

VMS recommends that all facets of promotion are considered in regulating the advertisement of cannabis in Vermont to ensure that advertising does not promote the use of cannabis, ensures that less than 15% of youth are exposed to cannabis advertising and that consumer protection, public health and public safety take priority over creating an industry dependent on developing new users.

Currently, Vermont has some of the highest rates of young adult use of marijuana in the country, with 38% of 18–25-year-olds using marijuana in the past 30 days. Among high school students, marijuana use during the past 30 days significantly increased from 24% in 2017 to 27% in 2019 and according to Andrea Villanti, PhD, MPH, from the Vermont Center on Behavior & Health at the University of Vermont, since the start of COVID-19, 50 percent of youth and young adult past 30-days users reported increasing their use of marijuana.⁴ As Vermont builds out a retail system for cannabis, increases the availability of cannabis statewide and normalizes marijuana use among adults, there is an increased risk of youth and young adult use rates rising even higher.

The data that Dr. Villanti cites shows a direct correlation with states that have legalized marijuana sales and a reduced perception of harm among youth and young adults. A CDC study from September 2020 looked at youth exposure to marijuana advertising after Oregon legalized retail sales of marijuana and found that about three-quarters of youths reported exposure to marijuana advertising, with exposure higher in youths in school districts with a closer average proximity to retail marijuana stores and persistent online exposure.⁵

¹<https://legislature.vermont.gov/Documents/2020/WorkGroups/House%20Health%20Care/Regulation%20of%20Cannabis/W~Kelly%20Dougherty~Health%20Impacts%20of%20Marijuana~1-24-2020.pdf>

² [https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366\(19\)30048-3/fulltext#seccestitle140](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(19)30048-3/fulltext#seccestitle140)

³ <https://www.cnn.com/2021/09/17/health/marijuana-vomiting-wellness/index.html>

⁴ [https://ccb.vermont.gov/sites/ccb/files/2021-07/2021-07-08%20Villanti%20-%20VT%20Cannabis%20Control%20Board%20\(002\).pdf](https://ccb.vermont.gov/sites/ccb/files/2021-07/2021-07-08%20Villanti%20-%20VT%20Cannabis%20Control%20Board%20(002).pdf)

⁵ https://www.cdc.gov/pcd/issues/2020/19_0206.htm

Retail marijuana storefronts were among the leading source of advertising seen by youths. While Oregon restricts advertising deemed attractive to minors, little else in the state's rules curb the influence of retail storefronts on social norms. Other states like Washington State, limits stores to 2 signs measuring a maximum of 1,600 square inches that may contain only the trade name, location, and nature of the business. A high level of online exposure persists in Oregon despite state-level regulations that restrict internet advertising to locations where at least 70% of the audience is 21 or older. Like tobacco advertising and alcohol advertising, marijuana advertising could work in the longer term to similarly increase the likelihood of initiation and heavier use among youths by fostering positive attitudes and expectations of cannabis use.

The Massachusetts' Cannabis Control Commission currently regulates approximately 150 cannabis retailers and similar to Vermont, requires that all forms of advertising are only visible to 15% of youth under the age of 21. In that state, if the retailer is found to be in violation of these exposure limitations, they are subject to a hefty fine. A recent article states that Massachusetts' cannabis retailers have turned to podcasts, digital streaming services and the use of high-profile influencers to market their products and that this is leading to "increased availability and rapid de-stigmatization."⁶

Specifically, the VMS recommends:

- a) The CCB work with the Vermont Department of Health and other public health experts to craft a robust advertising review to ensure that the percentage of Vermonters under the age of 21 exposed to cannabis promotion is 15 percent or less. Regulations should place the burden on the company advertising to prove that 85% of the audience is over 21. Given that age-gating has been shown in the context of e-cigarettes to be an inadequate barrier to youth viewing internet advertising, internet/digital/social media advertising should be prohibited unless and until an entity can demonstrate an effective method of ensuring over 85% of the audience is over 21;**
- b) The CCB creates an enforcement mechanism that includes fines for violating the advertising regulations and/or penalizes the licensee by making renewal of a license more difficult or no longer possible;**
- c) The warning labels and warning symbols should be featured prominently on all packaging, advertisement, point of sale flyer, website, spoken word promotion and branded products;**
- d) That the point-of-sale flyer be designed as a comprehensive warning document for the new user and should include evidence-based warnings by prevention and public health experts that includes the same information contained on the warning labels, discussed above, and information for parental users on how to protect children in the house with cannabis. The CCB should work with Vermont's Substance Misuse Prevention Council on an annual review of the POS flyer, to ensure up-to-date information is included; and example of effective consumer information can be found at https://www.med.uvm.edu/docs/cannabinoids_pt_handout_2019_07_26/ahec-documents/cannabinoids_pt_handout_2019_07_26.pdf?sfvrsn=a9452681**
- e) That cannabis business signs be included in the definition of advertising, and adopt limits such as Washington's to the number, size and content of business signs, as evidence shows**

⁶ <https://www.masslive.com/cannabis/2021/08/advertising-restrictions-lead-cannabis-companies-to-get-creative.html>

signs normalize the business and help establish the business as a recognizable brand for youth who live or attend schools within proximity of retail shops;

- f) That the CCB include in advertising restrictions all forms of social and digital media that are increasingly hard to regulate and that the DLL, and other enforcement entities, must be trained on how to enforce the advertising restrictions over social and media forms;
- g) That the CCB develop a “responsible retailer program” similar to Massachusetts’ program, that educates retailers on how to avoid inadvertently promoting to youth;
- h) That the CCB is responsible for creating a comprehensive data collection system that includes data on advertising volume, distribution of retail shops and dispensaries, counter-marketing strategies and particular forms of advertising trends in order to dovetail youth behavior and use rates, to inform future regulations and to create targeted education and prevention programs. The CCB should partner with the Substance Misuse Prevention Council and the Vermont Department of Health to ensure that this data is captured and reported annually.

(2) Should integrated licensees and product manufacturers licensees be permitted to produce solid concentrate products with greater than 60 percent THC for purposes of incorporation into other cannabis products?

Edible products containing cannabis extract are increasingly more popular and becoming a lucrative facet of the legalized market for both recreational and medicinal cannabis. According to cannabis trade group, BDSA, growth in the sales of edibles is outpacing the industry and the firm expects edibles to make up about 15 percent of the market by 2025.⁷ Consumers often choose edibles over cannabis smoking, as they perceive smoking to be more harmful and edibles to be the more safe and efficient way to achieve the therapeutic or euphoric effect of cannabis. Studies show that the delayed onset of the effect of cannabis in edibles can actually present a greater danger to new users who continue to consume more cannabis, before the drug has taken effect, which can result in adverse effects, including episodes of severe cannabis-induced behavioral impairment, extreme sedation, agitation, anxiety, cardiac stress, and vomiting. Higher doses of THC, or an “overdose of cannabis,” following the ingestion of an edible are also associated with temporary psychotic symptoms as hallucinations, delusions, and anxiety in some individuals.⁸

Edibles and the potency of THC found in commercial cannabis products has also led to increased emergency room visits. As found in an April 2019 study published in the Annals of Internal Medicine,⁹ records at a Colorado hospital show a three-fold increase in marijuana visits to the hospital, stressing an already burdened emergency department system. Seventeen percent of the visits were for uncontrolled bouts of vomiting, most often from inhaled marijuana.

A November 2020 report, published by the Washington State Prevention Research Subcommittee¹⁰, found that:

⁷ <https://www.preparedfoods.com/articles/125842-bdsa-growth-of-cannabis-edibles-outpaces-industry-growth>

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260817/#R9>

⁹ <https://www.cbsnews.com/news/after-legalization-marijuana-related-er-visits-climb-at-colorado-hospital/>,
<https://annals.org/aim/article-abstract/2729208/acute-illness-associated-cannabis-use-route-exposure-observational-study>

¹⁰ <https://adai.uw.edu/wordpress/wp-content/uploads/2020/11/Cannabis-Concentration-and-Health-Risks-2020.pdf>

- a) Young people are particularly vulnerable to negative effects of high potency cannabis.
- b) Negative effects from manufactured products are especially high among children, and exposure to vaping liquids is more likely to need medical intervention.
- c) Negative impacts are more acute for adolescents who use cannabis with high THC concentration or use these products more frequently.
- d) Use of cannabis with high THC concentration increases the chances of developing cannabis use disorder or addiction to cannabis, particularly among adolescents.
- e) High potency cannabis use can have lifelong mental health consequences, which often manifest in adolescence or early adulthood.
- f) Daily cannabis use, particularly of high potency products, increases the risk of developing a psychotic disorder, like schizophrenia, and is related to an earlier onset of symptoms compared to people who do not use cannabis.
- g) Among those with a psychotic disorder diagnosis, the use of high potency cannabis exacerbates disease symptoms.

Based on these factors, VMS strongly recommends that the Cannabis Control Board draft regulations that limit the potency of cannabis concentrates to below 60 percent THC, regardless of whether they are being added to products.

(3) Whether the Board should permit hemp or CBD to be converted to Delta-9 THC?

With the understanding that in order for hemp and hemp products to be sold legally, they can only contain .03% of Delta-9 THC and that some hemp producers are synthetically isolating the Delta-8 THC cannabinoid to enhance the psycho-activity of hemp and hemp products, VMS recommends that the CCB maintain the current ban on the use of synthetic cannabinoids in the production of any hemp product or hemp-infused product as prohibited by the Vermont Hemp Rules § 6.3, which were adopted in May of 2020.¹¹

In September of 2021, the Centers for Disease Control (CDC) put out a health advisory warning that the increased availability of products containing Delta-8 THC, which is a cannabinoid isomer synthetically produced from hemp (similar to Delta-9 THC), has led to increased reported cases of adverse events that have resulted in the hospitalization and/or emergency department treatment of consumers of these products.¹²

According to the CDC, the health effects of Delta-8 THC and other cannabinoid isolates have not been researched extensively and are not well-understood by regulators or consumers. Consumers who use these hemp products may experience unexpected or increased THC intoxication, as the total THC content is likely underestimated when they are generally sold as a legally produced hemp or CBD product. These products, which include vapes, gummies and infused chocolates, are also enticing to kids, as 39% (258 of 661 cases) of the adverse events reported in 2021 involved pediatric patients less

¹¹https://agriculture.vermont.gov/sites/agriculture/files/documents/PHARM/hemp/Vermont_Hemp_Rules_effective_05_21_20.pdf

¹² <https://emergency.cdc.gov/han/2021/han00451.asp>

than 18 years of age. Technically, as long as these products are derived from hemp and contain no more than 0.3% of Delta-9-THC, the limit under federal law, many state retailers and regulators consider them legal.

In April of 2021, the Vermont Agency of Agriculture, Foods and Markets published a clarification stating that while naturally occurring Delta-8 THC is not barred from hemp or hemp products, Vermont producers cannot manufacture the Delta-8 THC cannabinoid from hemp.¹³ Also, the Vermont Hemp Rules require solvent free mechanical extraction methods and prohibit the use of use of butane, propane, hexane and other hydrocarbons to isolate Delta-8 THC. According to the Chemical and Engineering News on August 30th, 2021, the synthetic solvents required to isolate the Delta-8 THC use “pretty aggressive” heavy metals and strong acids. A medicinal cannabis expert at the University of California San Diego said, “A lot of irresponsible production is going on in the sense that most of these people are getting their information from online forums, and many of them aren’t necessarily trained chemists.”¹⁴

The VMS recommends that the CCB maintain the prohibition of synthetically isolated Delta-9 THC from hemp or CBD, which converts to Delta-8 THC, as its health effects are largely unknown, and the chemicals used to isolate it are illegal and unhealthy.

(3) Recommendations for the Membership and Duties of the Cannabis Oversight Advisory Panel

VMS appreciates that it is appropriate to update the membership of the Cannabis for Symptom Relief Oversight Committee, especially as the program becomes less focused on enforcement and more focused on patient access to cannabis. VMS is supportive of removing reference to specific types of health care professionals who may serve on the Committee and stating that “two licensed health care professionals” shall serve on the Committee. However, VMS suggests that this read two licensed health care professionals “with knowledge of the use of cannabis for symptom relief” rather than “with knowledge of using cannabis as medicine” as cannabis continues to lack approval as a drug at the federal level. Further, VMS has concern with such members being chosen by lottery rather than a more systematic process for reviewing candidates for factors such as diversity in type of health care provider and knowledge of cannabis.

(4) Other Recommendations Regarding the Future Regulation of Cannabis for Symptom Relief

VMS generally believes that the cannabis for symptom relief program has been operating well, balancing patient need, public safety and scientific data. VMS submits for your consideration these additional comments regarding the cannabis for symptom relief program:

a) Maintain Review Board with Slight Modifications

In addition to the Cannabis for Symptom Relief Oversight Committee, the legislature established a Review Board to review denials of applications by patients as well as to “meet periodically to review studies, data, and any other information relevant to the use of cannabis for symptom relief. The Board may make recommendations to the General Assembly for adjustments and changes to this

¹³ <https://agriculture.vermont.gov/hemp-program/manufacture-delta-8-thc-or-its-use-hemp-products-permitted-under-vermont-hemp-program>

¹⁴ <https://cen.acs.org/biological-chemistry/natural-products/Delta-8-THC-craze-concerns/99/i31>

chapter.” 18 VSA § 4473 (b)(5)(A) & (B). VMS believes that the Board should continue to operate and fulfill these functions. Indeed, the Board should be used more robustly to review data on the use of cannabis for symptom relief as this function has not been well supported.

In addition, VMS recommends modifications to the composition of the Review Board. Currently, membership includes:

- (i) a physician appointed by the Medical Practice Board;
- (ii) a naturopathic physician appointed by the Office of Professional Regulation;
and
- (iii) an advanced practice registered nurse appointed by the Office of Professional Regulation.

This membership excludes many other professionals who might have knowledge of the use of cannabis for symptom relief, such as osteopathic physicians, pharmacists or physician assistants. VMS recommends the membership be stated as:

- (iv) Two health professionals licensed by the Board of Medical Practice,
appointed by the Board of Medical Practice
- (v) Two health professionals licensed by the Office of Professional Regulation,
appointed by the Office of Professional Regulation

b) Maintain a list of conditions for use; do not require “recommending” use

VMS opposes the use of cannabis under the program for “any disease, condition, or treatment.” Conditions should only be added to the Marijuana Registry program if peer-reviewed scientific research demonstrates that marijuana is safe and effective for a specific condition. According to a January 2017 review¹⁵ of the research, while there is strong evidence that marijuana may alleviate symptoms for some conditions, such as chronic pain and chemotherapy-induced nausea, there is very limited evidence of its usefulness for a host of other conditions, especially psychological conditions.

Marijuana contrasts with other medications which physicians can prescribe. Given marijuana’s continued status as a schedule I drug and restrictions on the ability to study marijuana, there is limited information regarding efficacy, indications for use and potential side effects. Physicians oppose being made into a gatekeeper for a substance for which they have limited information and evidence. Given the current state of research, patients and health professionals expect the program to be driven by data – please keep the registry a source that patients and health professionals can rely on. Marijuana is further distinguishable from other medications in that it is difficult to coordinate care involving marijuana use even for medicinal purposes: it does not show up in the Vermont Prescription Monitoring System, may not be documented in an EHR, and dose, type and mode of administration may be difficult or impossible to know. If one clinician is filling out the paperwork for any condition this may be unknown to all other clinicians involved in the care of the patient.

Physicians must also be cautious about crossing the legal line to “recommending” or “prescribing” marijuana. Having an undefined category of “any other” condition would put physicians closer to the line of documenting that they have made a determination that they are recommending marijuana for a given condition. We do not recommend that the program put physicians in this legal gray area.

¹⁵ <http://nationalacademies.org/hmd/~media/Files/Report%20Files/2017/Cannabis-Health-Effects/Cannabis-report-highlights.pdf>

Finally, expansion of the registry to non-evidence-based conditions becomes even less necessary when Vermonters can choose to legally grow or purchase cannabis for any purpose. If they desire cannabis for other indications, they have avenues to obtain it that do not involve health care providers.

c) Maintain a requirement for a bone fide 3-month health care professional-patient relationship

The Vermont Medical Society supports retaining the requirement for a 3-month health care professional-patient relationship before a health care professional can complete a verification form. Existing statute and program rules already provide a number of exceptions: for certain diagnoses, for patients moving to the state or changing health care providers and for recent diagnoses. 18 VSA § 4472 (1)(B). If there is no requirement for a bone fide health care professional relationship or required length of relationship, we anticipate that “marijuana mills” will appear where patients simply pay an examination fee and walk out with a verification form, as has been seen in Maine, Colorado, California and other states without the closely regulated program that Vermont has in place – and as attempted in Vermont in 2017.¹⁶ Further, patients may well obtain and continue use of cannabis with no ongoing monitoring for positive or harmful effects.

d) Ensure safe products and dosing

The Vermont Medical Society recommends that the Cannabis Control Board, informed by the Review Board, establish a clinically appropriate THC dose limit and concentration limit for THC-containing products sold by dispensaries, taking into consideration the 10 mg maximum dose established by the FDA for FDA-approved dronabinol (Marinol). There is no research proving any medical benefit above 15% THC and mental illness and addiction increases substantially with increasing THC limits. See e.g. Evaluation of THC-Related Neuropsychiatric Symptoms Among Adults Aged 50 Years and Older A Systematic Review and Metaregression Analysis, Velayudhan et al. JAMA Network Open. 2021;4(2):e2035913. doi:10.1001/jamanetworkopen.2020.35913. Further, VMS recommends that the CCB develop mandatory warning labels for medical products consistent with commercial products that address dosing, side effects and potential toxicity. Currently, Vermont law and regulations only require labels for medical products to address TCH in single dose edibles, strain and weight. See 18 VSA §4474e (h) and Rules for Regulating Cannabis for Symptom Relief § 6.6.

Thank you for considering our comments. Please let VMS know if you have any questions.

¹⁶ <http://digital.vpr.net/post/medical-marijuana-doctor-will-see-you-now-canna-care-connects-patients-pot#stream/0>